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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,536	11/28/2001	Jesus W. Casas-Bejar	P-7109.03 C1	6231

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EXAMINER

THISSELL, JEREMY

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,536

Applicant(s)

CASAS-BEJAR ET AL.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,26,30-32 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,26,30-32 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: _____

Art Unit: 3763

DETAILED ACTION

Claim 28

Applicant has cancelled claim 28, but has also submitted amendments therefor. After review of amended claim 28, it appears to differ from claim 26 only in the functional language of the preamble. The examiner has deduced that it was, in fact, Applicant's intent to cancel claim 28, and thus, it has not been examined, and remains cancelled.

Specification

The specification is objected to because of the list of references cited therein. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, or on Applicant's PTO-1449, they have not been considered. Further, since any references that are cited on either form PTO-892, or on Applicant's PTO-1449 will be printed on the face of any patent issuing herefrom, the listing in the specification is unnecessary and will be redundant. The list must be deleted from the specification.

Art Unit: 3763

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10, 32, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims contain subject matter somewhat contradictory to that in independent claims 1 and 30. Claims 1 and 30 set forth that the drug is "intimately mixed" into the polymer. However, claims 7-10, 32, and 35 appear to claim that the two are combined somewhat differently (e.g. claim 7 claims that the agent is "coated onto the tissue-contacting surface"). Applicant is requested to review these claims closely to determine if they indeed conflict with the claims from which they depend.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 11, 12, 26, 30-32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al (US 5,609,629).

Art Unit: 3763

Helmus teaches substantially all the claimed subject matter including an implantable medical device (figure 1, col. 3, line 31), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 55) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46).

Note that col. 7, lines 57-62 specify the OUTER layer, not the reservoir layer. In col. 7, lines 57-62, Helmus teaches that the agent in the outer layer is put there to produce a "gradual release effect" alluding to the slower release of the agent at first from the outer layer and gradual increase in the release rate as the more concentrated stores of the same agent start to seep through the outer layer from the inner reservoir layer. Since this teaches that the agent in the outer layer can be the same as in the inner layer, Helmus' teaching of the reservoir agent being a steroid (col. 6, line 55) is interpreted as referring to physiologically active agents in BOTH the reservoir and outer layer.

Helmus teaches all the claimed subject matter except for the steroid being a glucocorticosteroid such as dexamethasone. Fearnot teaches the use of dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 54-55) since dexamethasone is a well-known anti-inflammatory steroid, and as demonstrated by Helmus it is known to use it as the bioactive component of a bioactive surface on a catheter.

Art Unit: 3763

With regard to the method claims, claim 26, which claims a method of use, claims only one broad method step of "implanting," the rest is merely structure. Claims 30-32, and 35 merely claim the basic assembly steps necessary to put anything together (e.g. "coupling"). Again, the rest is merely structure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus in view of Fearnot as applied to claim 1 above, and further in view of Hendriks et al '151.

Helmus as modified by Fearnot teaches all the claimed subject matter of claim 23 except for the anti-inflammatory agent being covalently bonded to the polymer surface. Hendriks teaches a catheter (col. 4, line 8), having an anti-inflammatory agent (col. 4, lines 23-24), wherein the agent is covalently bonded to the surface of the catheter (col. 4, line line 33-35).

It would have been obvious to one of ordinary skill in the art to use the covalent bonding as taught by Hendriks to embed the anti-inflammatory agent of Chait as modified by Fearnot into layer 18 of Fearnot.

Response to Arguments

Applicant's attention is hereby called to the Examiner's remarks in parent application 09/063,227 in the office action rendered 6 February 2003.

Art Unit: 3763


Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt
February 8, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
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